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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/692,151

10/14/2003

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EXAMINER

HAQ, SHAFIQL

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/692,151		NOLAN ET AL.	
	Examiner	Art Unit		
	Shafiqul Haq	1641		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 14, 18, 24 and 29-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 14, 18 and 30-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24, 29 and 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/9/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to restriction/election

1. Applicants' response filed February 05, 2007 to election requirement in Office Action mailed October 04, 2006 is acknowledged and entered.
2. Applicants' election with traverse of Group V, Claims 24-28 is acknowledged. Applicant election of formula (A) and the species of SEQ ID No:15 (KPVQYWTQMFYT) is also acknowledged.

Applicants' traversal is on the grounds that subcombination claims may be subjected to restriction only if the combination claims do not require the particulars of subcombination claim for patentability. This is not found persuasive because of the reasons of record on pages 2 in Office Action of October 04, 2006, in which restriction was not based on combination and subcombination. In addition, the search for each of the distinct inventions of Groups I-V is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Finally, the condition for patentability is different in each case. A patentability determination for Invention I would require an assessment of the novelty and unobviousness of an 8 amino acids peptide capable of binding to a fluorophore while a patentability determination for invention II would require an assessment of the novelty and unobviousness of a complex of 8 amino acids peptide with a dye and patentability determination for Invention III would require an assessment of the novelty and unobviousness of method steps

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performed to bind a peptide to a fluorophore dye. Thus, it will be an undue burden to examine all the inventive Groups in one application.

3. Applicants incorporated new claims 29-42 of which claims 30-36 do not read on the elected species (SEQ ID NO:15). Accordingly, Claims 1-6, 14, 18, 30-37 (non-elected species) are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited supra be canceled in response to this Office action to expedite prosecution.
4. Therefore, claims 24, 29 and 37-42 with elected species (SEQ ID NO: 15) are examined on merits.

Claim objections

4. Claim 24 is objected to for containing non-elected subject matter. The claim should be amended to exclude non-elected subject matter, which falls within the scope of elected compound (SEQ ID NO: 15).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 39, 40, 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for binding of the peptides of claim 24 to Texas Red dye, however, not enabling for binding of the peptides

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of claim 24 to all fluorophore dyes encompassed by the term "fluorophore dye".

The term "fluorophore dye" encompasses Texas Red, Rhodamide dyes, Oregon Green dyes, fluorescein dyes, cyanine dyes, coumarin dyes and many other fluorescent dyes. The specification provides guidance and working examples for binding of peptides of claim 24 with Texas Red dye only. The description of the invention as it appears in the specification discloses interaction of peptides represented by formula of claim 24 with Texas Red dye only (see table 2, Table 3 and table 4) but there is not a single example or enabling disclosure in the specification that show or describe binding of peptides represented by the formula of claim 24 to any other fluorophore dyes except the Texas Red dye.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 38-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4, 7 and 10 of U.S. Patent No. 6,747,135 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of 135' patent discloses a complex of a fluorophore dye with a peptide of SEQ ID NO:15 which is encompassed by the peptide sequence of claim 24 of instant application. The patent also discloses a method of binding a peptide having SEQ ID NO: 15 with a fluorophore dye. Claims 38-42 are generic with respect to peptide sequence but the peptide sequence represented by the formula of claim 24 of instant application encompasses SEQ ID NO:15 of 135' patent.

Allowable subject matter

9. Elected species (SEQ ID NO: 15) of Claim 24 and dependent claims 29 and 37 are allowable. The following is a statement of reasons for the indication of allowable subject matter: Prior arts of record do not teach or fairly suggest a peptide comprising SEQ ID NO: 15.

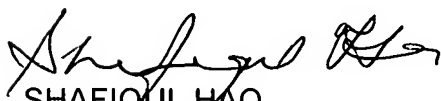
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Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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EXAMINER
ART UNIT 1641


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